REMARKS

Claim Rejections – 35 USC § 103

The Office has quoted the statute from 35 USC 103(a), which is referenced herein. The Office has rejected claims 32-39 as being unpatentable over Cutson et al. (Physical Therapy, 1995, Vol. 75, No. 5, pgs. 363-373) in view Silvestrini (US 4,132,791) and further view of Kent (The Lancet, 2000, Vol. 355, pgs. 911-918). Applicant has carefully considered the Office rejections and respectfully submits that the amended claims, as supported by the arguments herein, are distinguishable from the cited reference.

According to the MPEP §2143.01, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art."

A useful presentation for the proper standard for determining obviousness under 35 USC §103(a) can be illustrated as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims at issue;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

Obviousness cannot be established by combining prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. The mere fact that the prior art may be modified in the manner suggested by an examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

The Board of Patent Appeals and Interferences (BPAI) continues to reverse Examiners who can not explain "why a person of ordinary skill in the art would have found it obvious" to combine the references in the manner proposed by the Examiner." Furthermore, the Applicant notes that none of the references specifically recognized the advantages discussed in the present application.

"....[T]o establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. [*Rouffett,* 149 F.3d at 1355] In practice, this requires that the Board "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." Id. at 1357-59. This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the Graham test. When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used *hindsight* to conclude that the invention was obvious." *In re Kahn* (Fed. Cir. 2006, 04–1616).

Therefore, in formulating a rejection under 35 U.S.C. 5 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. (*see* USPTO Memo May 30, 2007 from Margaret A. Focarino, Deputy Commissioner for Patent Operations)

The Office correctly acknowledges that the cited Cutson reference fails to disclose any of the elements of independent claim 32, specifically the treatment of Parkinson's Disease with Nefazodone. The Office cites US Pat. No. 4,132,791 as teaching the treatment of Parkinson's with Trazodone, an antidepressant. The Office further acknowledges that while treatment with Trazodone is taught, treatment with Nefazodone is not. The Office relies upon the teaching of the Kent reference to allege an such similarity between Nefazodone and Trazodone as would make treatment of Parkinson's disease with Nefazodone obvious, yet must acknowledge that the Kent reference also fails to disclose the treatment of Parkinson's with either drug.

The applicant respectfully disagrees with the Office's analysis, and respectfully submits that it fails to accurately characterize the state of the art at the time of the filing of the claimed invention. This contention is further supported by the two references submitted in the concurrently filed Information disclosure statement, both of which indicate that at the time of the filing of the claimed invention, the use of Nefazodone, and for that matter Trazodone were

unlikely treatments for Parkinson's as both were reported, well after the '791 reference to induce or exacerbate, rather than treat Parkinson's.

Furthermore, The '791 reference, recounts essentially a clinical trial with a total of 13 patients with nicotine induced tremors, with only 10 patients showing positive results. My comparison, 4 placebo patients showed positive results. Thus, one skilled in the art would not necessarily accepted this trial as persuasive. This is contrasted with the report of Albanese published in 1988 showing a deterioration of Parkinson's patient being treated with Trazodone. (Albansese, A. *et al.* Can Trazodone induce Parkinsonism?, Clinical Neuropharmacology Vol. 11, No. 2, pp. 180-182, 1988)

The applicant further notes that the structurally similar Etoperidone, the agent forming the primary focus of the '791 reference produced different results from that of Trazodone. Importantly this underscores the inherent unpredictability of the action of structurally similar agents in the treatment of tremors.

The applicant respectfully submits that the similarities recited by the Kent reference are not relevant to the present discussion. The Office fails to provide evidence that the improved efficacy for depression noted by Kent is related to Parkinson's disease, or that the structural similarity between the chemicals renders the substitution of Nefazodone for Trazodone to be of predictable benefit, assuming for the sake of argument that one skilled in the art would set aside evidence that these drugs would exacerbate the symptoms of Parkinson's disease.

Additionally, references forming the basis of the Office's rejection have been in the public for many years, as have the chemical agents recited in the references. Parkinson's disease is well known to be a debilitating and as yet, incurable disease with treatments having limited efficacy. An efficacious treatment for Parkinson's would seemingly be the prototypical long felt need. The applicant respectfully submits that to the best of its knowledge there has been no commercial treatment of Parkinson's disease with Nefazodone.

The applicant submits that perhaps the strongest evidence for the non-obviousness of the use of Nefazodone in the proposed treatment is the letter to the editor of Benazzi, published in the International Journal of Geriatric Psychiatry Vol. 12, 1195, Dec. 1997 wherein the author reported a case where Nefazodone worsened Parkinson's symptoms in a patient. While this is an anecdotal letter, it is unambiguous evidence that the state of the art had not concluded that by the dates of the cited references that Nefazodone was an obvious treatment for Parkinsonism.

The applicant respectfully submits that at least for the above reasons, claim 32 is patentably distinct from the cited references, either alone or in combination. The therefore submits that claim 32 and those claims depending therefrom are in condition for allowance.

Applicant believes the above amendments and remarks to be fully responsive to the Office Action, thereby placing this application in condition for allowance. No new matter is added. Applicant requests speedy reconsideration, and further requests that Examiner contact its attorney by telephone, facsimile, or email for quickest resolution, if there are any remaining issues.

Respectfully submitted,

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